IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. **Wilderness Family Naturals, LLC**, a limited liability company, and **KENNETH H. FISCHER**, and **ANNETTE C. FISCHER**, individuals, Defendants.	**CIVIL NO. 08-cv-06241 (DWF/RLE)** **UNOPPOSED MOTION TO VACATE CONSENT DECREE OF PERMANENT INJUNCTION AND MEMORANDUM IN SUPPORT**

UNOPPOSED MOTION TO VACATE CONSENT DECREE OF PERMANENT INJUNCTION

Wilderness Products, L.L.C., a successor to the corporate Defendant, Wilderness Family Naturals, L.L.C., together with individual defendants, Kenneth H. Fischer and Annette C. Fischer (collectively "Defendants"), hereby move this Court for an Order vacating the Consent Decree of Permanent Injunction ("Consent Decree") in its entirety pursuant to paragraph 22 of that Decree. *See* Dkt. 2 (entered on December 8, 2008). Granting this motion will be permanently close the matter and terminate the Court's continuing jurisdiction over the controversy. Plaintiff, the United States of America, does not oppose the motion.

MEMORANDUM IN SUPPORT

On December 8, 2008, this Court entered the Consent Decree in the above matter. A copy of the Consent Decree is hereto attached as Exhibit A. Paragraph 22 of the Consent Decree contemplates this Court vacating the Consent Decree after Defendants have complied with its terms, the Federal Food, Drug, and Cosmetic Act ("FDCA"), and all applicable U.S. Food and Drug Administration ("FDA") regulations. Specifically, paragraph 22 states:

> No sooner than sixty (60) months after entry of this Decree, Defendants may petition FDA for leave to ask this Court to dissolve this Decree. If during such sixty (60) month period, Defendants have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations, FDA will grant such petition and Defendants may request that this Decree be dissolved.

Ex. A at ¶ 22.

The Consent Decree has now been in effect for more than sixty (60) months, and since September 10, 2010, the Defendants have complied with all of the terms of the Consent Decree and the FDA has not notified the Defendants of a significant violation of the FDCA, FDA regulations, or the Consent Decree. Pursuant to paragraph 23 of the Consent Decree, this Court retains jurisdiction to grant such relief.

Roger Gural, Trial Attorney, Consumer Protection Branch, U.S. Department of Justice, and Jonelle Eshbach, Associate Chief Counsel, Office of General Counsel, United States Food and Drug Administration, advised counsel for

Defendants that the United States does not oppose granting this Motion. Furthermore, before filing this motion, counsel for Defendants provided copies of the Motion and Proposed Order to government counsel.

For the reasons stated above, Defendants move for entry of an order granting this Unopposed Motion to Vacate the Consent Decree of Permanent Injunction.

Dated: May 12, 2016

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. WILDERNESS FAMILY NATURALS, LLC, a limited liability company, and KENNETH H. FISCHER, and ANNETTE C. FISCHER, individuals, Defendants.	)	CIVIL NO. 08-6241 (DWF/RLE) CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, having commenced this action by filing its Complaint for Permanent Injunction ("Complaint") against Wilderness Family Naturals, LLC ("Wilderness Family"), a limited liability company, and Kenneth H. Fischer and Annette C. Fischer, individuals (hereafter, collectively, "Defendants"), and Defendants solely for the purposes of settlement of this case, and without admitting or denying the allegations in the Complaint, having appeared and consented to the entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while held for sale after shipment in interstate commerce.

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are

permanently restrained and enjoined from introducing or delivering for introduction into interstate commerce, causing to be introduced or delivered for introduction into interstate commerce, holding for sale after shipment in interstate commerce, and manufacturing, packing, processing, and distributing, Chickweed Salve, St. John's Wort Salve, Chest Rub Salve, Goldenseal-Comfrey Salve, flux hull lignan, Green Food Feast, any coconut oil product, and any other product that is a new drug within the meaning of the Act, 21 U.S.C. § 321(g), unless and until:

A. An approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to the product; or

B. An investigational new drug application ("IND") filed pursuant to 21 U.S.C. § 355(i) is in effect for the product and it is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the protocol as authorized as part of the IND application; or

C. Defendants have

(1) removed all claims from the product's labels, labeling, promotional materials, and websites or other media owned or controlled by Defendants, that the product is intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease, or otherwise cause the product to be a drug within the meaning of the Act; and

(2) removed, from the product labels, labeling, promotional materials, and websites owned or controlled by Defendants, references to, endorsements, or adoptions of any other website that conveys information about any of Defendants' products that demonstrates that the product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or otherwise causes the product to be a drug within the meaning of the Act.

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded; and

C. Violates 21 U.S.C. § 331(k), by causing an article of drug to become misbranded while held for sale after its shipment in interstate commerce.

8. Within fourteen (14) calendar days of entry of this Decree, Defendants shall retain an independent person or persons (the "expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for each of their products on their product labels, labeling, promotional material, and any internet websites owned or controlled by Defendants including, but not limited to websites referenced, endorsed, or adopted directly or indirectly by Defendants ("expert review").

A. At the conclusion of the expert review, the expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants continue to have any claims on their product labels, labeling, promotional materials, websites owned or

controlled by Defendants or in any other media, including, but not limited to websites referenced, endorsed, or adopted directly or indirectly by Defendants, that cause any of their products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g). The expert shall submit this report concurrently to FDA and Defendants within thirty (30) calendar days of the entry of this Decree.

B. If the expert reports any violations of the Act, Defendants shall, within seven (7) business days of receipt of the report, correct all of the violations. If Defendants believe they are unable to correct all of the violations within seven (7) business days, Defendants shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty-one (21) calendar days. Defendants shall correct the violations in accordance with their proposed schedule, unless FDA notifies Defendants that a shorter time frame is required.

C. An expert review shall be conducted annually for no less than three years after the completion of the initial review described in this paragraph. Defendants may use the same expert for each expert review.

D. For each expert review, the expert shall submit his or her report concurrently to FDA and Defendants within ten (10)

business days from the completion of the review. If the expert reports any violations of the Act, Defendants shall, within seven (7) business days of receipt of the report, correct all of the violations. If Defendants believe they are unable to correct all of the violations within seven (7) business days, Defendants shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty-one (21) calendar days. Defendants shall correct the violations in accordance with their proposed schedule, unless FDA notifies Defendants that a shorter time frame is required.

E. If the expert does not report any violations of the Act for three consecutive expert reviews, Defendants may request, in writing, at the address specified in paragraph 18, to discontinue the periodic expert reviews.

9. Within thirty (30) calendar days of entry of this Decree, Defendants shall submit to FDA a certification of compliance, signed by each of the individually-named Defendants in this matter, each Defendant stating that he or she: (a) has personally reviewed all of Defendants' product labels, labeling, promotional materials, and internet websites owned or controlled by Defendants or websites referenced, endorsed, or adopted directly or indirectly by Defendants; and (b) personally

certifies that the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act and applicable regulations and do not include claims that the products cure, mitigate, treat, and/or prevent disease. Thereafter, Defendants shall submit certifications of compliance every four(4) months for a period of no less than three (3) years. At the end of the three (3) year period of certifications, Defendants may request, in writing, at the address specified in paragraph 18, to discontinue the periodic certifications or to change the length of time between certifications. Upon receipt of Defendants' certification, FDA may notify Defendants that it disagrees with the certification and list the reasons for disagreement, citing any violations of the Act, if applicable, in which case, Defendants shall, within seven (7) business days of notification, correct all of the violations. If Defendants believe they are unable to correct all of the violations within seven (7) business days, Defendants shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty-one (21) calendar days. Defendants shall correct the violations in accordance with their proposed schedule, unless FDA notifies Defendants that a shorter time frame is required.

10. Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all of Defendants' products in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

11. Within five (5) business days of FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any internet websites owned or controlled by Defendants, or websites referenced, endorsed, or adopted directly

or indirectly by Defendants including, but not limited to www.wildernessfamilynaturals.com, www.regaininghealthnaturally.com, and www.healthinformationlibrary.com, Defendants shall submit a copy of the requested materials to FDA at the address specified in paragraph 18.

12. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, analyses of Defendants' product labels, labeling, promotional materials, or websites owned or controlled by Defendants, or websites referenced, endorsed, or adopted directly or indirectly by Defendants that convey information about Defendants' products, a report prepared by Defendants' expert, or any other information, that Defendants have violated the Act, applicable regulations, or this Decree, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, or this Decree, FDA may, as and when it deems necessary, direct Defendants, in writing, to take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any article(s);

B. Submit additional reports or information to FDA;

C. Recall any article(s) at Defendants' expense; or

D. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and this Decree.

13. Any cessation of operations as described in paragraph 12 shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act, applicable regulations, and this Decree, and that Defendants may resume operations.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. For the purposes of this Decree, inspections include FDA's review and analysis of Defendants' claims for their products in the product labels, labeling, promotional materials, and any and all websites owned or controlled by Defendants, and any and all websites referenced, endorsed, or adopted directly or indirectly by Defendants that convey information about Defendants' products. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $81.61 per hour and fraction thereof per representative for inspection work; $97.81 per hour or fraction

thereof per representative for analytical or review work; $0.585 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. FDA will submit an invoice for such costs to Defendants, and Defendants shall submit payment, payable to the U.S. Treasury, to FDA at the address specified in paragraph 18 within thirty (30) calendar days of receipt of such invoice.

15. Within ten (10) business days of entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities)(hereafter collectively referred to as "associated persons"). Within twenty (20) calendar days of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and

identifying the names and positions of all associated persons who have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Decree, with new associated persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

16. Within ten (10) business days of entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at each of their manufacturing or distribution facilities, and shall ensure that the Decree remains posted for as long as it remains in effect.

17. Defendants shall notify the District Director, FDA Minneapolis District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant Wilderness Family, or in the sale or assignment of any business assets, such as buildings,

equipment, or inventory, but excluding the sale of inventory that is the normal course of Defendants' business, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership. Defendants shall notify the District Director, FDA Minneapolis District Office, in writing at least five (5) business days before Defendants' creation of any new website or Defendants' reference, endorsement, or adoption directly or indirectly of a website that conveys information about Defendants' products.

18. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA Minneapolis District Office, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401.

19. If any of Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America the sum of one thousand dollars ($1,000) in liquidated damages for each violation and an additional one thousand dollars

($1,000) for each day on which a violation occurs, so long as such violation(s) continues. For the purposes of this paragraph, a "violation" is defined as each time any Defendant introduces or delivers for introduction into interstate commerce any product that is accompanied by (on the product's label, labeling, promotional materials, websites owned or controlled by Defendants, or in any other media that Defendants own, operate, control, and/or have referenced, endorsed, or adopted) a claim(s) that causes the product to be a drug within the meaning of the Act, unless the product is the subject of an approved application, pursuant to 21 U.S.C. § 355(b) and (j).

20. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

21. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. No sooner than sixty (60) months after entry of this Decree, Defendants may petition FDA for leave to ask this Court to dissolve this Decree. If during such sixty (60) month period, Defendants have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations, FDA will grant such petition and Defendants may request that this Decree be dissolved.

23. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Dated this 8th day of December, 2008.

s/Donovan W. Frank
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

s/Kenneth H. Fischer
KENNETH H. FISCHER, on behalf of Wilderness Family Naturals, LLC, and Individually

s/ Annette C. Fischer
ANNETTE C. FISCHER, on behalf of Wilderness Family Naturals, LLC, and Individually

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